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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,814	03/26/2004	Suman Preet Khanuja	US 1374/04	8540

7590 11/13/2008
Law Office - Dinesh Agarwal, P.C.
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5350 Shawnee Road
Alexandria, VA 22312

EXAMINER

CALAMITA, HEATHER

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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11/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,814

Applicant(s)

KHANUJA ET AL.

Examiner

HEATHER G. CALAMITA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

Status of Application, Amendments, and/or Claims

1. Claims 1-12 are pending. Claims 3-9 are withdrawn as being directed to non-elected subject matter. Claims 1, 2, 10, 11 and 12 are under examination. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "The oligonucleotide as claimed in claim 1, wherein the domain is from 241 to 261 nucleotide position of *gyr A* gene from translation start site of *E. coli*. SEQ ID NO: 1 recited in claim 1 is 21 nucleotides long. The domain recited in claim 2 is 20 nucleotides in length. The relationship of the domain recited in claim 2 to SEQ ID NO: 1 in claim 1 is unclear. The oligonucleotide of claim 2 is 20 nt in length and is stated to be the same as the oligonucleotide of claim 1. The oligonucleotide of claim 1 is 21 nt in length. It is unclear how the oligonucleotide of claim 2 can be the same as the oligonucleotide of claim 1 if the oligonucleotide of claim 1 is required to be 21 nt in length.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. (Mol Gen Genet., 1988).

With regard to claims 10-12, Yoshida et al. teach SEQ ID NOs 3 and 4 (see p. 4 and the alignment below).

SEQ ID NO: 3 1 AATTTGCGACCTTTGAATCCG 21

Yoshida et al. 137 AATTTGCGACCTTTGAATCCG 157

SEQ ID NO: 4 1 CTGGGTCTGGGAGTAGAGGTTG 22

Yoshida et al. 1158 CTGGGTCTGGGAGTAGAGGTTG 1137

With regard to the rejections of claims 10-12 over Yoshida, Yoshida et al. teach the nucleotide sequences comprising SEQ ID NOs 3 and 4 respectively. The recitation of "for identifying the alpha-artether resistance conferring domain in the *gyrA* gene of *E. coli*" is a recitation of intended use as this merely states one of the many things for which the oligonucleotides may be used.

Response to Arguments

4. Applicants' arguments filed July 31, 2008, have been fully considered but they are not persuasive. Applicants' arguments regarding the 112 second paragraph are not persuasive. Applicants argue claim 2 recites a specific embodiment of the sequence recited in claim 1. This argument is not persuasive because as explained in the rejection above the relationship is unclear. Claim 2 is not simply an embodiment of claim 1. The oligonucleotide of claim 2 is 20 nt in length and is stated to be the same as the oligonucleotide of claim 1. The oligonucleotide of claim 1 is 21 nt in length. It is unclear how the oligonucleotide of claim 2 can be the same as the oligonucleotide of claim 1 if the oligonucleotide of claim 1 is required to be 21 nt in length.

With respect to the rejections over Yoshida et al., Applicants argue the claim recites the primers are for identifying the ADR in the *gyrA* gene of *E. coli* and this recitation makes the claims novel over

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Yoshida et al. This argument is not persuasive because the aforementioned recitation is merely a recitation of intended use and does not structurally distinguish the instantly claimed oligos over the oligos disclosed by Yoshida et al. Additionally, the claim language used is that of comprising not consisting, so additional elements may be present in the prior art oligonucleotides. Furthermore, these are primer sequences for a known gene. It is well known by a skilled artisan how to choose primers for a known sequence. In the absence of unexpected results it would be obvious for a skilled artisan to choose primers for a known gene sequence.

Allowable Subject Matter

5. Claim 1 is allowed. SEQ ID NO: 1 is free of the prior art.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system

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nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199

/GARY BENZION/

Supervisory Patent Examiner, Art Unit 1637